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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,656	04/08/2004	David K. Gong	31176282-004001	8010

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,656	GONG ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 29-52 are pending. Applicants have cancelled original claims 1-28. Claims 29-52 are new. Receipt and consideration of Applicants' remarks/arguments submitted on January 29, 2007 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 29, 2007 has been entered.

Moot Rejections/objections

All rejections and/or objections of claims 1-28 cited in the previous office action mailed on July 27, 2006 **are moot**, because said claims /have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 36, and 43-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The cited claims contain new matter as follows: (1) the pressure value of "approximately 50 psi" in claims 32, 36, 43, 47, 50 and claims dependent therefrom lacks written support in the specification, because the only pressures mentioned in the specification are 40 psi and 60 psi in paragraph [0064]; (2) a spray drying temperature range of "between 60 °C and 70 °C" in claims 32, 36, 43, 47, 50, and claims dependent therefrom lacks written support in the specification, because the only spray drying temperatures mentioned in the specification are 60 °C and 70 °C; (3) a flow rate of "approximately 18 standard cubic feet per minute (scfm)" in claims 32, 36, 43, 47, 50, and claims dependent therefrom lacks written description, because the only flow rate supported in the specification is 17.8 scfm; and (4) transferring spray dried FIX to a sealed container at less than 5% humidity lacks support, because the specification only describes said step undertaken at a relative humidity of less than 5% (see paragraph [0065]). Humidity and relative humidity, although similar, are not equivalent.

The remaining claims are rejected for depending upon a rejected claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 29-36 and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29, 33, and 40 are vague and indefinite, because it is unclear what is meant by "slowly maximally inhaling," because this term is not defined in the instant specification. Thus, an ordinary skilled artisan would be unable to ascertain the intended metes and bounds of "slowly maximally inhaling."

The remaining claims are rejected for depending upon a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-31, 33-35, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lechuga-Ballesteros et al. (WO 01/32144; From IDS; "Lechuga") in view of Kurachi et al. (*Blood Coagulation and Fibrinolysis*, **1993**, *4*, 953-974; provided with the office action mailed on July 27, 2006) ("Kurachi") for the reasons of record set forth on pages 4-7 of the office action mailed on February 21, 2006 and further articulated on page 5 of the office action mailed on July 27, 2006.

Response to Arguments

Applicant's arguments filed January 27, 2006 have been fully considered but they are not persuasive. Applicants' traversal arguments regarding the cited references applied to new claims 29-31, 33-35, and 37-42 are based on their assertions that (1) the sequestration effect offered by monomeric Factor IX (FIX) is allegedly an unexpected result not described by the cited references; (2) although native FIX may be monomeric *in vivo*, there is no reason to expect it to remain monomeric and active when formulated as a dry powder; and (3) the cited references do not describe a prophylactic treatment method utilizing FIX.

These arguments are found unpersuasive for the reasons of record, which will be reiterated here. Argument (2) is unpersuasive, because Applicants have not provided any data to demonstrate that the FIX utilized by Lechuga is not monomeric. The cited references do not teach the sequestration effect observed by Applicants; however, the observation of an unknown property belonging to a known formulation is not novel. It is the Examiner's position that the cited references teach the compositions disclosed by Applicants and used in the claimed methods (see above-cited pages of the office actions mailed on February 21, 2006 and July 27, 2006) and that the FIX present in the dry powders taught by Lechuga is monomeric. Furthermore, the Lechuga reference does fairly suggest the inhalation and aerosolization of dry powders comprising FIX. Therefore, it would be reasonably expected that aerosolization and inhalation of the prior art FIX dry powders would exhibit the same effects as observed by practicing Applicants' claimed methods, because the inhaled powders are the same or obvious variants of one another. The step of allowing aerosolized FIX to deposit in the deep lung is a passive step and obviously would result from the inhalation of aerosolized FIX dry powder as taught by the

prior art and claimed by Applicants. The step of exhalation, although not explicitly taught, obviously occurs because it is impossible for one to inhale and not subsequently exhale, unless the inhaling subject is no longer living. Regarding the requirement that inhalation occur "slowly and maximally," this limitation has been given little weight because the instant specification provides no guidance or description of what constitutes slow maximal inhalation (see the above rejection under 35 U.S.C.§ 112, 2nd paragraph). Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 32, 36, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lechuga in view of Kurachi as applied to claims 29-31, 33-35, and 37-42 above, and further in view of Huang et al. (U.S. Patent No. 6,280,729; "Huang").

Applicant Claims

Applicants claim (1) a method of preventing hemophilic bleeding in advance of a bleeding event; (2) a prophylactic method of treating hemophilia; (3) a blister pack containing FIX, wherein the methods comprise (i) aerosolizing monomeric FIX, (ii) inhaling aerosolized FIX, (iii) allowing said monomeric FIX to deposit in the deep lung, and/or (iv) exhaling, wherein said monomeric FIX is sequestered in the deep lung and wherein the FIX used in the claimed methods and contained in the claimed blister pack is made by a process comprising (i)

diafiltering a concentrated FIX solution to a concentration of 12 mg/ml, (ii) spray drying the diafiltered solution, and (iii) transferring spray dried FIX to a sealed container.

NOTE: Product-by-process limitations in a claimed composition or method of treatment are given little weight unless the claimed process results in a structurally different product. In the instant case, only the step of diafiltering is deemed as yielding a product that is structurally different. Therefore, this step is addressed below in the instant rejection.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Lechuga and Kurachi have been set forth previously on pages 4-7 of the office action mailed on February 21, 2006 and on page 5 of the office action mailed on July 27, 2006.

Huang teaches the preparation of Factor IX (title; abstract; col. 3, lines 45-55; col. 8, line 33 through col. 11, line 43). Specifically, Huang teaches that according to the prior art it is known and desirable to remove salt from FIX solutions to obtain a solution that is osmotically compatible with human tissues and this salt removal is routinely achieved via ultrafiltration and **diafiltration** (col. 4, lines 5-14 and 43-48; col. 9, lines 46-56; col. 10, lines 16-49). The routine nature of diafiltration of FIX solutions is especially evident in the below text:

> Typically, the bound factor IX is washed, and then eluted from the anion exchange resin using a buffered salt solution of high molarity. Inasmuch as such high molarity salt solution is considered osmotically incompatible with human tissues, practitioners of the prior art invariably subject their factor IX extracts to dialysis and filtration (or alternately ultrafiltration and diafiltration) which place the factor IX extract in concentrated form, but replace the high molarity salt solution with a physiologically-compatible low molarity salt solution.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Lechuga and Kurachi lack the teaching of diafiltration. This deficiency is cured by the teachings of Huang.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Lechuga and Kurachi to diafilter solutions of FIX prior to spray drying, because it is undesirable to administer composition that are osmotically incompatible with human tissues. An ordinary skilled artisan would have been motivated to diafilter a FIX solution; because in the routine purification of FIX one obtains high molarity buffered salt solutions and said salt solutions are osmotically incompatible with human tissues. Furthermore, an ordinary skilled artisan would have been motivated to diafilter a FIX solution, because this is a conventional step used in the purification of FIX solutions. Regarding the other steps in making the FIX dry powders utilized in the claimed methods, the prior art teaches spray

drying (see Lechuga) and Applicants have not demonstrated the criticality of spray drying at a pressure of approximately 50 psi between a temperature of 60 °C and 70 °C at a rate of 5 ml/min and approximately 18 scfm. Regarding the step of transferring FIX to a sealed container at less than 5% humidity, the prior art teaches that the dry powder formulations are preferably maintained under dry (i.e. relatively low humidity) conditions during manufacture, processing, and storage (Lechuga, pg. 19, lines 18-20). A humidity of less than 5% reads on "relatively low humidity conditions." Notwithstanding this, Applicants have not demonstrated the criticality of the transfer step occurring under an atmosphere having humidity of 5% or less. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lechuga in view of Kurachi and Huang as applied to claims 32, 36, and 43-45 above, and further in view of Russell, K. E. et al. (IDS).

Applicant Claims

Applicants claim a blister pack containing recombinant monomeric FIX, wherein said monomeric FIX is made by a process comprising (i) diafiltering a concentrated FIX solution to a concentration of 12 mg/ml, (ii) spray drying the diafiltered solution, and (iii) transferring spray dried FIX to a sealed container.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Lechuga and Kurachi have been set forth previously on pages 4-7 of the office action mailed on February 21, 2006 and on page 5 of the office action mailed on July 27, 2006. The teachings of Huang have been set forth above in the instant office action. The teachings of Russell were set forth on pages 10-11 of the office action mailed on February 21, 2006.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Lechuga, Karachi, and Huang with the teachings of Russell and utilize recombinant FIX, because Russell is in the same field of endeavor as Lechuga, Karachi, and Huang and suggests the inhalation administration of recombinant FIX to treat hemophilia. A skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings because Russell demonstrated that intratracheal administration of recombinant FIX to hemophilia B dogs resulted in systemic circulation and achieved detectable and therapeutic levels beginning between 2 and 8h post infusion and lasting at least 72 h. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lechuga in view of Kurachi and Huang as applied to claims 32, 36, and 43-45 above, and further in view of DeFrees et al. (US 2004/ 0137557) (cited with the office action mailed on February 21, 2006).

Applicant Claims

Applicants claim a dry powder comprising glycosylated monomeric FIX, wherein said monomeric FIX is made by a process comprising (i) diafiltering a concentrated FIX solution to a concentration of 12 mg/ml, (ii) spray drying the diafiltered solution, and (iii) transferring spray dried FIX to a sealed container.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Lechuga and Kurachi have been set forth previously on pages 4-7 of the office action mailed on February 21, 2006 and on page 5 of the office action mailed on July 27, 2006. The teachings of Huang have been set forth above in the instant office action. The teachings of DeFrees were set forth on pages 11-14 of the office action mailed on February 21, 2006.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Lechuga, Karachi, and Huang with the teachings of DeFrees and utilize a glycosylated Factor IX in Lechuga's aerosolizable formulations, because glycosylation is well known in the medical arts for engendering a particular physiological

response. A skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because glycosylation of peptides is well known in the medical arts, the attachment of PEG to a peptide has been shown to reduce peptide immunogenicity, and PEG has been attached to a peptide via a glycosyl moiety. Regarding the amounts of ingredients in the rejected claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-26 of U.S. Patent No. 6,835,372 (USPN '372; formerly copending 10/313,343) in view of Lechuga and further in view of Kurachi and Huang. Applicants claim a blister pack comprising FIX as described above in the instant office action. Dependent claim 24 of USPN '372 claims a composition comprising a di- or tripeptide selected from the group including dileucine and trileucine and an active agent selected from a group including Factor IX (i.e. FIX). Claim 25 of USPN '372 states that the composition is in the form of a dry powder and claim 25 of USPN '372 states that said composition is a spray-dried dry powder. The cited claims of USPN '372 lack an explicit teaching of the degree of monomeric FIX, a blister pack, and that the powders are made by a process in which FIX is diafiltered at a concentration of 12 mg/ml and subsequently spray dried under specific conditions. These deficiencies are cured by the teachings of Lechuga (set forth on pages 4-7 of the office action mailed on February 21, 2006), Kurachi (on page 5 of the office action mailed on July 27, 2006), and Huang (set forth in the instant office action), which have been set forth on the record as indicated. In summary, Lechuga teaches spray drying methods for making FIX dry powders from aqueous solutions in which said dry powders preferably have a moisture content below 10% w/w. Lechuga's teachings do not require the use of ethanol. Lechuga also teaches

the storage of said dry powders in a blister pack. Kurachi teaches that biologically active FIX is monomeric. It is the Examiner's position that the FIX in the claimed dry powders of USPN '372 is inherently monomeric, absent evidence to the contrary. Huang demonstrates that it is conventional procedure to purify FIX solutions using diafiltration. Regarding the specific spray drying parameters, it is the Examiner's position that an ordinary skilled artisan upon routine optimization of spray drying protocols would readily achieve arrive at the claimed parameters. Applicants have not demonstrated the criticality of the claimed spray drying parameters. Thus, the Examiner concludes that an ordinary skilled artisan would have found the cited claims of the instant application prima facie obvious over the cited claims of USPN '372.

Claims 43-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-24 of copending Application No. 10/313,961 (copending '961) in view of Lechuga and further in view of Kurachi and Huang. Applicants' claims have been described above. Dependent claim 22 of copending '961 claims a pharmaceutical formulation comprising dry particles of Factor IX (FIX), wherein (i) the FIX dry particles have a size of about 0.1 microns to about 10 microns and a MMAD from about 1.0-5.0 microns; (ii) the formulation has a moisture content of less than about 10% w/w; and (iii) the particles are made from a spray dried aqueous solution. The cited claims of copending '961 lack an explicit teaching of the degree of monomeric FIX, a blister pack, and that the powders are made by a process in which FIX is diafiltered at a concentration of 12 mg/ml and subsequently spray dried under specific conditions. These deficiencies are cured by the teachings of Lechuga (set forth on pages 4-7 of the office action mailed on February 21, 2006),

Kurachi (on page 5 of the office action mailed on July 27, 2006), and Huang (set forth in the instant office action), which have been set forth on the record as indicated. In summary, Lechuga teaches spray drying methods for making FIX dry powders from aqueous solutions in which said dry powders preferably have a moisture content below 10% w/w. Lechuga's teachings do not require the use of ethanol. Lechuga also teaches the storage of said dry powders in a blister pack. Kurachi teaches that biologically active FIX is monomeric. It is the Examiner's position that the FIX in the claimed dry powders of copending '961 is inherently monomeric, absent evidence to the contrary. Huang demonstrates that it is conventional procedure to purify FIX solutions using diafiltration. Regarding the specific spray drying parameters, it is the Examiner's position that an ordinary skilled artisan upon routine optimization of spray drying protocols would readily achieve arrive at the claimed parameters. Applicants have not demonstrated the criticality of the claimed spray drying parameters. Thus, the Examiner concludes that an ordinary skilled artisan would have found the cited claims of the instant application *prima facie* obvious over the cited claims of copending '961.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 43-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 25-26, and 30 of copending Application No. 10/985,509 (copending '509) in view of Lechuga and further in view of Kurachi and Huang. Applicants' claims have been described above. Dependent claim 22 of copending '509 claims a dry powder composition comprising an active agent and a di- or

tripeptide comprising at least two leucines, wherein the active agent is selected from a group including Factor IX (FIX). Independent claim 25 of copending '509 claims a method wherein a liquid formulation comprising an active agent and a di- or tripeptide comprising at least two leucines is dried to obtain a dry powder comprising said active and di- or tripeptide. Claim 30 of copending '509 specifies that the drying process used be selected from a group including spray drying. The cited claims of copending '509 lack an explicit teaching of the degree of monomeric FIX, a blister pack, and that the powders are made by a process in which FIX is diafiltered at a concentration of 12 mg/ml and subsequently spray dried under specific conditions. These deficiencies are cured by the teachings of Lechuga (set forth on pages 4-7 of the office action mailed on February 21, 2006), Kurachi (on page 5 of the office action mailed on July 27, 2006), and Huang (set forth in the instant office action), which have been set forth on the record as indicated. In summary, Lechuga teaches spray drying methods for making FIX dry powders from aqueous solutions in which said dry powders preferably have a moisture content below 10% w/w. Lechuga's teachings do not require the use of ethanol. Lechuga also teaches the storage of said dry powders in a blister pack. Kurachi teaches that biologically active FIX is monomeric. It is the Examiner's position that the FIX in the claimed dry powders of copending '509 is inherently monomeric, absent evidence to the contrary. Huang demonstrates that it is conventional procedure to purify FIX solutions using diafiltration. Regarding the specific spray drying parameters, it is the Examiner's position that an ordinary skilled artisan upon routine optimization of spray drying protocols would readily achieve arrive at the claimed parameters. Applicants have not demonstrated the criticality of the claimed spray drying parameters. Thus,

the Examiner concludes that an ordinary skilled artisan would have found the cited claims of the instant application *prima facie* obvious over the cited claims of copending '509.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants did not address the merit of any of the rejections on the record previously made on the ground of nonstatutory obviousness-type double patenting as applied to the new claims in their reply submitted on January 29, 2007. Thus, the above rejections on the ground of nonstatutory obviousness-type double patenting are deemed proper as applied to the new claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following prior art references are considered relevant because these demonstrate the diafiltration of Factor IX solutions is a routine procedure in the purification of Factor IX: U.S. Patent No. 5,286,849 (Herring; Title, abstract; col. 4, lines 42-51) and U.S. Patent No. 5,714,583 (Foster et al.; Title, abstract; col. 5, lines 61-65; col. 6, lines 1-37; Figure 1 in column 6; and col. 8, lines 37-43).

Claims 29-52 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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